

EXHIBIT I

CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

Sidney D. Williams, M.D.

I. PREAMBLE

Sidney D. Williams ("Williams") agrees to enter into this Corporate Integrity Agreement (the "Agreement") to provide for the establishment of a Corporate Integrity Program to assure compliance with the billing requirements of Medicare, Medicaid and all other federal health care programs by Williams, his employees and third parties with whom Williams contracts. The Corporate Integrity Program shall be maintained so as to ensure, to the extent reasonably possible, that Williams and each of his employees and contractors maintain the business integrity required of a participant in federal health care programs, and that Williams' billings for medical care are in compliance with all statutes and regulations applicable to such programs and with the terms of this Agreement as set forth below. The Agreement shall include the provisions listed below. Williams will do everything he can do in his capacity to ensure compliance with the terms of this Agreement.

II. TERM OF THE AGREEMENT

The period of compliance obligations assumed by Williams under this Agreement shall be five (5) years from the effective date of this Agreement (Date: May 29, 1998).

III. CORPORATE INTEGRITY PROGRAM

Within ninety (90) days of the date of execution of this Agreement, Williams agrees to: (I) implement a Corporate Integrity Program (the "Program"), which shall include the provisions listed herein; and (ii) provide the Office of Inspector General of the Department of Health and Human Services' ("OIG's") Office of Counsel to the Inspector General ("OCIG") with a report demonstrating that Williams has complied with all of the Program's requirements. This report, known as the "Implementation Report," shall be sent to the address set forth in section VIII of this Agreement.

Within the first thirty (30) days following the effective date of this Agreement, Williams shall post in a prominent place accessible to all patients and employees a notice detailing its commitment to comply with all applicable statutes, regulations and directives applicable to Medicare, Medicaid and all other federal health care programs in the conduct of its business. Williams shall submit a copy of this notice in the Implementation Report.

A. INFORMATION AND EDUCATION

Within the first (60) days following the effective date of this Agreement, Williams and all personnel involved in preparing or submitting Medicare, Medicaid, and all other federal health care program bills shall be trained in the proper billing standards, methods, and procedures to insure accurate billing for services rendered to these federal health care programs. The training shall be designed to ensure that Williams and any other appropriate officer, director and employee is aware of all applicable health care laws, regulations, and standards of business conduct that such individual is expected to follow and the consequences both to the individual and Williams that will ensue from any violation of

such requirements. In addition, Williams will arrange for all new personnel involved in billing for services to participate in such training no later than thirty (30) days after they begin working for Williams. Until they have had the requisite training, such new employees will work under the direct supervision of an employee who has received such training. This training program shall provide for no less than four (4) hours annually of training for each person.

At a minimum, this training program shall cover the following topics:

1. The proper billing standards and procedures for the submission of accurate bills for services rendered and/or items provided to Medicare;
2. All applicable laws, rules, regulations, and guidelines related to Medicare and Medicaid billing, reimbursement, and the legal sanctions for improper billing; and
3. All applicable laws, rules, regulations, and guidelines related to health care fraud and abuse and the legal sanctions for violating these laws.

Williams will submit in the Implementation Report and future Annual Reports, certification from all appropriate personnel that they received, read, and understood the applicable health care laws, including Medicare laws, regulations and standards of business conduct.

B. PERSONAL SERVICES AND BUSINESS CONTRACTS

As part of the Implementation report and Annual Reports, Williams shall provide to OIG copies of all documentation reasonably relating to personal services and business contracts entered into by Williams, including, but not limited to, contracts with suppliers of medical equipment and services, related to Williams' delivery of medical services. OIG review of such contracts will be for the purpose of ensuring that such contracts were not designed to induce the unlawful referral of Medicare or Medicaid patients, in violation of the Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the Federal Physician Self Referral Prohibition (also known as the "Stark Statute") (codified at 42 U.S.C. § 1395nn). To that end, Williams shall seek to ensure that all such contracts in which he enters on behalf of the Williams Clinic complies with the following standards:

1. The agreement shall be set out in writing and signed by the parties;
2. The agreement shall specify the services to be provided by the agent;
3. If the agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement shall specify exactly the schedule of such intervals;
4. The terms of the agreement shall be for not less than one year;
5. The aggregate compensation paid to the agent over the term of the agreement shall be set in advance, be consistent with fair market value in arms-length transactions and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid and other federal health care programs, as defined in section 1128B(f) of the Social Security Act (42 U.S.C. § 1320a-7b(f));
6. The services performed under the agreement shall not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and

7. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

C. INDEPENDENT AUDITS

Within thirty (30) days from the effective date of this Agreement, Williams will contract with a 3rd party reviewer (audit, law or health care consulting firm) to undertake a review of a statistically valid sample of the claims submitted by him and his agents and employees to the Medicare program to determine that they are in compliance with the billing requirements of Medicare, Medicaid and all other federal health care programs. This review will be conducted by an independent and appropriately trained person or entity with knowledge of federal health care statutes, regulations, program requirements, billing policies and procedures. The results of this review shall be submitted with the Implementation Report as well as a corrective action plan for correcting any deficiencies found.

Also, for five (5) years from the effective date of this agreement, Williams agrees to undertake an annual review of a statistically valid sample of the claims submitted by him and his agents and employees to the Medicare program to determine that they are in compliance with the billing requirements of Medicare, Medicaid and all other federal health care programs. This review will be conducted by an independent and appropriately trained person or entity with knowledge of federal health care statutes, regulations, program requirements, billing policies and procedures.

Generally, if any of these reviews result in material billing deficiencies, Williams shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare intermediary), as appropriate, within thirty (30) days of discovering the deficiency and take remedial steps within sixty (60) days (or such additional time as may be agreed to by the carrier) to correct the problem, including preventing the deficiency from reoccurring. For purposes of this Agreement, a "material billing deficiency" shall mean anything that has a significant, adverse financial impact upon the Medicare, Medicaid, and any other federal health care program, which may be the result of an isolated event or a series of occurrences, and which lacks conformity with the particular health care program's reimbursement principles or other applicable statutes, and the regulations and directives issued by the Health Care Financing Administration ("HCFA"), its agents, or any other agency involved in the administration of the affected health care program.

Specifically, contemporaneous to Williams' notification to the applicable agency involved in the administration of the affected health care program as provided above, if any audits conducted pursuant to this Agreement reveal material billing deficiencies in Williams' Medicare and Medicaid billing processes, as well as the billing processes applicable to the other federal health care programs in which Williams participates, Williams shall notify OCIG of: (i) its findings concerning the material billing deficiency; (ii) Williams' actions to correct such material billing deficiency; and (iii) any further steps Williams plans to take to address such material billing deficiency and prevent it and similar billing deficiencies from reoccurring.

While this reporting requirement focuses on occurrences having a "significant," adverse financial impact, this provision does not excuse Williams' statutory obligation as a participant in the federal health care programs to bring to a payor's attention any other billing deficiencies, however de minimis, make appropriate refunds and take any steps necessary to prevent the reoccurrence in the future.

In the first Annual Report and in all future Annual Reports, Williams will include a complete description of the findings made during the reviews conducted pursuant to this section, a description of the corrective steps and proof of refund to the pertinent payor (where applicable), and a complete description of the methodology behind any repayments made as a result of these reviews (where applicable).

IV. SUBMISSION OF NERVE CONDUCTION MEDICARE CLAIMS

Williams shall not submit claims for services relating to current perception threshold tests and nerve conduction studies (including but not limited to CPT Codes 95900, 95903, and 95904) to Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)).

V. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Williams will report to OIG any reliable evidence of actions that Williams, after promptly considering such evidence with outside consultants or counsel, believes constitute a probable violation of any state or federal civil or criminal law, regulation, or rule governing a federal health care program. When such disclosure is required by the Agreement, Williams shall make the required disclosure as soon as practicable, but, in no event, later than thirty (30) calendar days after becoming aware of the existence of the probable violation. The evidence to be disclosed under this paragraph will include evidence relating to conduct by any of Williams' personnel and any person or entity with a financial interest in Williams' business, and it will include evidence disclosed to Williams from any source. Notwithstanding any other provision of this Agreement, any disclosures of information obtained by Williams from his legal counsel shall not constitute a waiver of the attorney-client privilege. Williams will certify to OIG that all disclosures made under this paragraph have been fully investigated and that appropriate actions have been taken to ensure that Williams is in compliance with all state and federal civil, criminal, and administrative laws, regulations and rules governing all federal health care programs. Nothing in this paragraph waives OIG's right to enforce any and all laws and regulations governing any federal health care program, subject to the release provisions of the Settlement Agreement signed this same date.

VI. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Williams' books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) Williams' compliance with the terms of this Agreement; and (ii) Williams' compliance with the requirements of the Medicare, Medicaid and other federal health care programs. The documentation described above shall be made available by Williams at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of Williams' employees who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. Williams agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Williams' employees may elect to be interviewed with or without a representative of Williams present. The OIG, HCFA, or the affected intermediary or carrier, may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Williams' compliance with the statutory and

regulatory requirement of Medicare, Medicaid and all other federal health care programs.

VII. ANNUAL REPORTS

Williams shall make annual reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures Williams has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

- (1) A description of the training programs implemented pursuant to section III.A of this Agreement and a summary of the activities engaged in, in furtherance of the training programs, including a schedule and topic outline of the training sessions.
- (2) A certification from Williams' attorney that all contracts in which Williams entered on behalf of the Williams Clinic complied with the requirements set forth in section III.B.
- (3) Copies of all documentation reasonably relating to personal services and business contracts entered into by Williams as set forth in section III.B.
- (4) A complete description of the findings made during the reviews conducted pursuant to section III.C of this Agreement relating to the year covered by the Annual Report, a description of the corrective steps and proof of refund to the pertinent payor (where applicable), and a complete description of the methodology behind any repayments made as a result of these reviews (where applicable).
- (5) A certification that the requirements set forth in section IV were met.
- (6) A certification that Williams has disclosed all probable violations pursuant to section V.
- (7) A resolution from Williams certifying that he has reviewed the annual report and agrees with the statements made therein.

Where applicable, the report shall include a statement that no events identified in subparagraphs (1) through (6) of this section occurred. Each Annual Report shall be submitted on the anniversary date of the execution of this Agreement for its duration as set forth in section VIII of this Agreement.

VIII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

ATTN: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax 202.205.0604

IX. DOCUMENT AND RECORD RETENTION

Williams shall maintain for inspection documents and records relating to Medicare, Medicaid and all other federal health care program reimbursement for a period of six (6) years following the execution of this Agreement.

X. BREACH AND DEFAULT PROVISIONS

Williams' compliance with the terms and conditions in this Agreement shall constitute an element of Williams' present responsibility with regard to participation in federal programs. Full and timely compliance by Williams shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Williams. As stated below in section XII of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Williams engages in conduct that OIG considers to be a material breach of this Agreement, OIG may seek exclusion of Williams from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon making its determination, OIG shall notify Williams of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Williams shall have thirty-five (35) days from the date of the letter to proceed as follows:

- (1) cure the alleged material breach; or
- (2) demonstrate to the OIG's satisfaction that: (a) Williams is in full compliance with this Agreement; or (b) the material breach cannot be cured within the thirty-five (35) day period, but that Williams has begun to take action to cure the material breach, that Williams will pursue such an action with due diligence, and that Williams will give the OIG a timetable for curing the material breach.

If at the conclusion of the thirty-five-day period (or other specific period as subsequently agreed by OIG and Williams), Williams fails to cure the material breach to OIG's satisfaction, Williams agrees to its immediate exclusion from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material billing violation, take corrective action and pay the appropriate refunds, as provided in section III.C; (ii) a failure to meet the billing requirements that pertain to current perception threshold tests and nerve conduction studies set forth in section IV; (iii) a failure to report a probable violation as provided in section V of this Agreement; or (iv) repeated or flagrant violations of the obligations under this Agreement.

In connection with the OIG's determination to exclude Williams pursuant to this provision, Williams shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in section X.B of this Agreement.

B. DISPUTE RESOLUTION

Upon OIG's delivery to Williams of its Intent to Exclude Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, Williams shall be afforded some review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the exclusion sought pursuant to this Agreement. Specifically, the OIG's determination to demand to seek exclusion shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The administrative law judge's decision, in turn, may be appealed to HHS's Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a breach of this Agreement shall be: (i) whether Williams was in material breach of one or more of his obligations under this Agreement; and (ii) whether such breach was continuing on the date of the Intent to Exclude Letter. For purposes of the exclusion herein agreed to in the event of breach of this Agreement, the administrative law judge's decision shall be deemed to make the exclusion effective, at which time the OIG may proceed with its exclusion of Williams, if the administrative law judge finds in favor of the OIG. The administrative law judge's decision may be appealed to the DAB in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

Neither the review by an administrative law judge nor the potential subsequent review of the administrative law judge's decision by the DAB, as provided for above, shall be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision shall be considered final for all purposes under this Agreement and shall not be appealed either administratively or judicially or otherwise be subject to review by any court or other adjudicative forum.

All notices required under any of the aforementioned proceedings shall be given to the OIG in accordance with section VIII of this Agreement.

XI. COSTS RELATED TO ADDITIONAL AUDITS

In addition to the obligations assumed by Williams under the Agreement and as described above, if OIG determines that it is necessary to conduct an independent audit or review to determine whether or to the extent to which Williams is complying with its obligation under this Agreement, Williams agrees to pay for the reasonable cost of any such audit or review.

XII. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Williams and the OIG agree as follows:

- (1) this Agreement shall be binding on the successors, assigns and transferees of Williams;
- (2) this Agreement shall become final and binding only upon signing by each respective party hereto; and
- (3) any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

SIDNEY D. WILLIAMS M.D.

05-23-98
Date

Sidney Williams M.D.
Sidney D. Williams, M.D.

5-23-98
Date

Sidney Williams Esq
Sidney Williams, Esquire
Counsel for Sidney D. Williams

OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

5/29/98
Date

L. Morris
Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services